IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Our File:	758/13131.19
Applicant:	Horst G. ZERBE et al.
Serial Number:	10/542,983
Filed:	July 21, 2005
Group Art Unit:	1615
Examiner:	---
Title:	ORAL DOSAGE FORMULATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
U.S.A.

REQUEST FOR CORRECTED FILING RECEIPT

Sir :

It is respectfully requested that the following correction be entered:

On the Filing Receipt, in section "Domestic Priority Data as Claimed by Applicant", the International Filing Date of PCT Application No. PCT/CA04/00073 should be changed from 02/12/2004 to 01/21/2004 (January 21, 2004) as seen on the first page of the publication of the PCT application, a copy of which is attached hereto for your convenience.

The above error, made by the Applicant, is clerical and typographical in nature.

It is respectfully requested that the above-indicated correction be made of record in the present patent application.

The Patent Office is hereby authorized to charge any fee related to the recordation of the above-mentioned correction to Deposit Account № 07-1742.

Respectfully submitted,

GOUDREAU GAGE DUBUC

Date: May ~~19~~ 25, 2006

by:_____
Alain M. Leclerc, Reg. No. 37,036

GOUDREAU GAGE DUBUC
Stock Exchange Tower
Suite 3400, P.O. Box 242
800 Place Victoria
Montreal, Quebec, Canada
H4Z 1E9
Tel.: (514) 397-7675
Fax: (514-397-4382

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/542,983	07/21/2005	1615	450	AML/13131.19		20	1

CONFIRMATION NO. 7824

25545
GOUDREAU GAGE DUBUC
800 PLACE VICTORIA, SUITE 3400
MONTREAL, QUEBEC, H4Z 1E9
CANADA

FILING RECEIPT

OC000000018234536

Date Mailed: 03/10/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Horst G. Zerbe, Hudson, QC, CANADA;
Pompilia Szabo, Greenfield Park, QC, CANADA;

Power of Attorney: The patent practitioners associated with Customer Number **25545**.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/CA04/00073 ~~02/12/2004~~ 01/21/2004
which claims benefit of 60/441,156 01/21/2003

Foreign Applications

REÇU
RECEIVED
30 MAR. 2006
GOUDREAU GAGE DUBUC
3400 TOUR DE LA BOURSE
C.P. 242 PLACE VICTORIA
MONTRÉAL, QUÉBEC H4Z 1E9
397-7602

Projected Publication Date: 06/15/2006

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Oral dosage formulation

Preliminary Class

514

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/542,983	Horst G. Zerbe	AML/13131.19

INTERNATIONAL APPLICATION NO.	
PCT/CA04/00073	
I.A. FILING DATE	PRIORITY DATE
~~02/12/2004~~ 01/21/2004	01/21/2003

25545
GOUDREAU GAGE DUBUC
800 PLACE VICTORIA, SUITE 3400
MONTREAL, QUEBEC, H4Z 1E9
CANADA

CONFIRMATION NO. 7824

371 ACCEPTANCE LETTER

OC000000018234537

Date Mailed: 03/10/2006

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

07/21/2005	07/21/2005
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 07/21/2005
- Copy of the International Search Report filed on 07/21/2005
- Preliminary Amendments filed on 07/21/2005
- Oath or Declaration filed on 07/21/2005
- Request for Immediate Examination filed on 07/21/2005
- U.S. Basic National Fees filed on 07/21/2005
- Assignment filed on 07/21/2005
- Priority Documents filed on 07/21/2005

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

DARRELL C COTTMAN
Telephone: (703) 308-9140 EXT 203

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

REVISED VERSION

(19) World Intellectual Property Organization
International Bureau

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5 August 2004 (05.08.2004)

PCT

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(21) International Application Number:
PCT/CA2004/000073

(22) International Filing Date: 21 January 2004 (21.01.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/441,156 21 January 2003 (21.01.2003) US

(71) Applicant *(for all designated States except US)*: SMARTRIX TECHNOLOGIES INC. [CA/CA]; 16751 TransCanada Road, Kirkland, Quebec H9H 4J4 (CA).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ZERBE, Horst, G. [CA/CA]; 714 Main Road, Hudson, Quebec J0P 1H0 (CA). SZABO, Pompilia [CA/CA]; 461 Boyd Avenue, Greenfield Park, Quebec J4V 1S4 (CA).

(74) Agents: DUBUC, J. et al.; Goudreau Gage Dubuc, Stock Exchange Tower, 800 Place Victoria, Suite 3400, P.O. Box 242, Montreal, Quebec H4Z 1E9 (CA).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

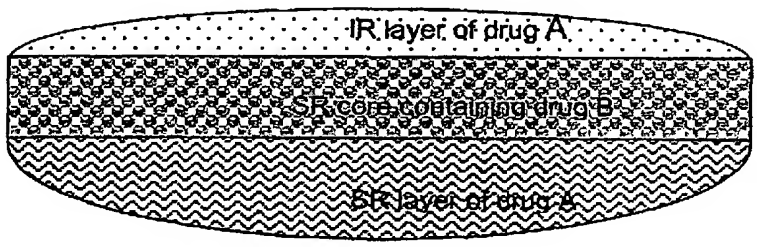
(88) Date of publication of the revised international search report: 30 September 2004

(15) Information about Correction:
see PCT Gazette No. 40/2004 of 30 September 2004, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2004/064815 A1

(54) Title: ORAL DOSAGE FORMULATION



(57) Abstract: A multi-layer oral dosage form, preferably a tablet, comprising a matrix core comprising a therapeutically effective amount of a first drug (NSAID), wherein the matrix core allows sustained release of the first drug; a first layer, which is in contact with the matrix core, comprising a first portion of a pharmaceutically effective amount of a second drug (H_2-blocker antagonist) , wherein the first layer allows sustained release of the second drug; and a second layer, which is in contact with said matrix core, comprising a second portion of the second drug, wherein the second layer allows immediate release of the second drug. Methods for preparing the multi-layer dosage form are also disclosed.